the afternoon, the committee will discuss particulates that appear in allergen extracts and the effect of these particulates on the safety and efficacy on these products. In closed session, the committee will receive a report on the status of an investigational new drug application and product license application supplement.

Procedure: On March 5, 2001, from 8:30 a.m. to 3:30 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by February 17, 2001. Oral presentations from the public will be scheduled between approximately 11:10 a.m. and 11:40 a.m., and between approximately 2:40 p.m. and 3:10 p.m. on March 5, 2001. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 21, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On March 5, 2001, from approximately 3:30 p.m. to 5 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). This portion will be closed to permit discussion of these materials.

FDA regrets that it was unable to publish this notice 15 days prior to the March 5, 2001, Allergenic Products Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Allergenic Products Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 14, 2001.

Bonnie H. Malkin,

Special Assistant to the Senior Associate Commissioner.

[FR Doc. 01–4230 Filed 2–20–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0057]

Determination That Bethanechol Chloride Injection and Tablets Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that bethanechol chloride 5 milligrams (mg) per milliliter (mL) injection and bethanechol chloride 5-, 10-, 25-, and 50-mg tablets, all formerly marketed by Merck & Co., Inc. (Merck), were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDA's) for bethanechol chloride drug products, and it will also allow FDA to continue to approve ANDA's for bethanechol chloride drug products.

FOR FURTHER INFORMATION CONTACT: Wayne H. Mitchell, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (the 1984 amendments) (Public Law 98–417), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. Sponsors of ANDA's do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug to which the ANDA refers.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162). Under § 314.161(a)(2) (21 CFR 314.161(a)(2)) the agency must make a determination as to whether a listed drug was withdrawn from sale for reasons of safety or effectiveness if ANDA's that refer to the drug that was withdrawn are approved. Section 314.161(d) provides that if FDA determines that the listed drug was removed from sale for safety or effectiveness reasons, the agency will begin proceedings to withdraw approval of the ANDA's that refer to the drug that was withdrawn from sale.

FDA has received a letter, dated April 7, 2000, from Merck, holder of NDA 6–536 for bethanechol chloride 5-mg/mL injection and bethanechol chloride 5-, 10-, 25-, and 50-mg tablets, stating that Merck has withdrawn those products from sale. Danbury Pharmacal, Inc., Roberts Laboratories, Inc., Glenwood, Inc., and Sidmak Laboratories, Inc. (Sidmak), all hold approved ANDA's that refer to one or more of Merck's bethanechol chloride drug products. Merck sold its bethanechol chloride drug products under the trade name of Urecholine. In their April 7, 2000, letter, Merck also informed FDA that Merck has assigned the trademark Urecholine to Sidmak for use in the sale of Sidmak's bethanechol chloride drug products.

FDA has reviewed its records and, under § 314.161, has determined that bethanechol chloride 5-mg/mL injection and bethanechol chloride 5-, 10-, 25-, and 50-mg tablets were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will list Merck's bethanechol chloride 5-mg/mL injection and bethanechol chloride 5-, 10-, 25-, and 50-mg tablets in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. The approval status of the ANDA's that refer to bethanechol chloride 5-mg/mL injection and bethanechol chloride 5-, 10-, 25-, and 50-mg tablets is unaffected. ANDA's for bethanechol chloride 5-mg/mL injection and bethanechol chloride 5-, 10-, 25-, and 50-mg tablets may be approved by the agency.